K052072
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AUG 2 9 2005

ABBOTT SPINE, INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Abbott Spine (formerly Spinal Concepts, Inc.)
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	Noah Bartsch Specialist, Regulatory Affairs Telephone: 512.533.1840 Fax: 512.918.2784
DATE:	July 29, 2005
TRADE NAME:	SC-AcuFix Ant-Cer Dynamic Anterior Cervical Plate System
COMMON NAME:	Spinal Fixation System
CLASSIFICATION NAME:	KWQ: Spinal Intervertebral Body Fixation Orthosis
CLASSIFICATION REFERENCE:	21 CFR § 888.3050
PREDICATE DEVICE:	Spinal Concepts, Inc. (now Abbott Spine, Inc.) Ant-Cer Dynamic Anterior Cervical Plate System, K024326, cleared January 23, 2003.

DEVICE DESCRIPTION:
The SC-AcuFix Ant-Cer Dynamic Anterior Cervical Plate System consists of bone plates, screws, and instruments to be used for anterior fixation to the cervical spine. The plate system features a dynamic design that allows for uni-axial motion in compression to ensure postoperative load sharing between the plate and the graft.

INDICATIONS:
The SC-AcuFix Ant-Cer Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

1. Degenerative disc disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
2. Trauma (including fractures);
3. Tumor;
4. Spondylolisthesis;
5. Spinal stenosis;

6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.

COMPARISON TO PREDICATE DEVICE:

The subject device is the result of design modifications to the predicate device, has the same intended use, and is substantially equivalent to the predicate device.

PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):

NON-CLINICAL PERFORMANCE AND CONCLUSIONS:

Laboratory and bench testing results demonstrate that the proposed Ant-Cer device is substantially equivalent to the predicate device.

CLINICAL PERFORMANCE AND CONCLUSIONS:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2005

Mr. Noah Bartsch
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K052072
Trade Name: SC-AcuFix™ Ant-Cer™ Dynamic Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: July 29, 2005
Received: August 1, 2005

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K052072**

Device Name:

The SC-AcuFix™ Ant-Cer™ Dynamic Cervical Plate System

Indications for Use:

The SC-AcuFix Ant-Cer Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

1. Degenerative disc disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
2. Trauma (including fractures);
3. Tumor;
4. Spondylolisthesis;
5. Spinal stenosis;
6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052072